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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,614	04/27/2006	Yvonne Paterson	P-7772-US	4019

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	PAPER NUMBER
1645	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,614	PATERSON ET AL.	
	Examiner	Art Unit	
	GINNY PORTNER	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-21 and 23-30* is/are pending in the application.

4a) Of the above claim(s) *10-19 and 28-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2,5-9,20-21,23-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-2, 5-21, 22-30 are pending.

Rejections/Objections Withdrawn

1. Specification The abstract of the disclosure now commences on a separate sheet in accordance with 37 CFR 1.52(b)(4).
2. Claims 1-3, 9 rejected under 35 U.S.C. 102(b) as being anticipated by Mora et al US Patent 3,328,252 is herein withdrawn in light of the claim limitation from original claim 4 having been incorporated into independent claim 1, thus obviated the prior art rejection.
3. Claims 1,3,7,9, are rejected under 35 U.S.C. 102(b) as being anticipated by Mankoski et al (1999), is herein withdrawn in light of the claim limitation from original claim 4 having been incorporated into independent claim 1, thus obviated the prior art rejection.
4. Claims 1-3, 7-9 are rejected under 35 U.S.C. 102(a) as being anticipated by Kleanthous et al (2001), is herein withdrawn in light of the claim limitation from original claim 4 having been incorporated into independent claim 1, thus obviated the prior art rejection.
5. The rejection of claims 1-9, 20-27 under 35 U.S.C. 102(b) as being anticipated by Frankel et al (US Patent 6.099,848) is herein withdrawn in light of the claims having been amended to recite the phrase "repeating step a), step b) and step c) with the harvested bacterial vaccine vector", which is not taught in Frankel et a", thus obviating the prior art rejection.
6. The rejection of claims 1-9 , 20-27 under 35 U.S.C. 102(a) as being anticipated by WO 01/25399 A2 (reference of record, sited on US PTO 1449). is herein withdrawn in light of the claims having been amended to recite the phrase "repeating step a), step b) and step c) with the harvested bacterial vaccine vector", which is not taught in Frankel et a", thus obviating the prior art rejection.

Response to Arguments/ Election/Restrictions

7. Applicant's arguments filed March 19, 2008 have been fully considered but they are not persuasive. Applicant asserts that the instantly claimed invention evidences unity of invention and maintaining the restriction is improper and in view of the forgoing amendments and remarks, the claims are allowable.

1. Applicant's remarks, and claim amendments have been fully considered, but are not convincing in light of new grounds of rejection set forth below.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 1, 2, 5-9, 20-21,23-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Pawelek et al (US Pat. 6,685,935, effective filing date June 4, 1996).

Pawelek et al disclose the instantly claimed invention comprising the steps of:

Instant claims 1, 7-8, 20, 25-26:

Step A) **Administering** (col. 16, line 48 "inoculated into the mouse")

To an animal (col. 16, line 30 "mammals", line 33 "mice")

Bacterial vaccine vector (col. 8, lines 9-24 "Vectors useful for the methods of the present invention include but are not limited to Borrelia burgdorferi, Brucella melitensis, Escherichia coli, enteroinvasive Escherichia coli, Legionella pneumophila, **Salmonella** typhi, **Salmonella** typhimurium, Shigella spp., Streptococcus spp., Treponema pallidum, Yersinia enterocoltica, Chlamydia trachomatis, Listeria monocytogenics, Mycobacterium avium, Mycobacterium bovis, Mycobacterium tuberculosis, BCG, Mycoplasma hominis, Rickettsiae quintana, Cryptococcus neoformans, Histoplasma capsulatum, Pneumocystis carnii, Eimeria acervulina, Neospora caninum, Plasmodium falciparum, Sarcocystis suihominis, Toxoplasma gondii, Leishmania

amazonensis, Leishmania major, Leishmania mexacana, Leptomonas karyophilus, Phytomonas spp., Trypanasoma cruzi, Encephahtozoon cuniculi, Nosema helminthorum, Unikaryon legeri.)

Step B) **Passaging** the bacterial vaccine vector through the animal (see col. 16, lines 48-51"microorganism becomes co-localized with the tumor and/or infects the tumor cells"; also see claim 9)

Step C) **Harvesting** the bacterial vaccine vector (see section 6.1.2 "Cycling the microorganism through solid tumors in vivo", see col. 16, line 51-63

tumor cells, the mice are sacrificed, the tumors excised, weighed and homogenized. An aliquot may be diluted into the proper microorganism growth medium and incubated at the proper growth conditions for 1-2 population doublings to insure the recovery of viable microorganisms for successive inoculations into tumor bearing mice. Further, if the isolated population is to undergo successive inoculations in tumor bearing mice, upon each successive inoculation, the number of microorganisms in the inoculate and the time of infection may be reduced to increase the stringency of selection for tumor-specific isolates. Additionally, the isolated popula- ")

Step D) repeating steps A-C with the harvested bacterial vaccine vector to enhance the immunogenicity

(See detailed description paragraph 274," Salmonella .... stimulated a host cellular immune response to the tumor cells. Enhancement of tumor immunity is thus another potential advantage in the use of parasites as tumor-specific therapeutic vectors." ; "release of the lipopolysaccharide (LPS) endotoxin by Gram negative bacteria such as Salmonella triggers release of tumor necrosis factor, TNF, by cells of the host immune system, such as macrophages, Christ et al., 1995, Science 268:80-83. Elevated TNF levels in turn initiate a cascade of cytokine-mediated reactions which culminate in the death of tumor cells.(Summary text paragraph12),

Also see claim 141. The method according to claim 135 wherein the super infective, tumor specific microorganisms are produced by: (a) exposing a mammal to having a solid tumor cell cancer to a microorganism for a time sufficient so that the microorganism can infect the tumor cells; (b) allowing the microorganism to replicate, thereby producing super-infective, tumor specific microorganisms; and (c) isolating the super-infective, tumor specific microorganisms from the infected tumor cells. And claim 145145. The method according to claim 139, 140, 141 or 142 further comprising: (c) repeating steps (a) and (b) a desired number of times.

and the bacterial vaccine vector expresses a **heterologous antigen** (ie col. 80, claim 21 col. 12, lines 25-26, Salmonella typhimurium clone 72 containing the HSV TK gene (clone #72.sup.5-3-2); also see Detailed Description Text (63): In another embodiment of the present invention, the desired genes expressed from the **expression constructs** are under the specific regulatory control of certain types of promoters.) Also see Listeria see col. 89, claim 135-136, claim 141, claim 143 "genetically engineered", see claim 145 "repeating" claim 141,

described the use of *Listeria monocytogenes* as a vaccine for the immunization of mice against lethal challenges with tumor cells expressing the same antigen expressed by the Listeria vaccine. In addition, they showed regression of established tumors when immunized after tumor development in an antigen specific T-cell-dependent manner.

see col. 4, lines 30-33;

Instant claim 2, 21: the organ is a liver , see claim 148, "The present invention is directed to the isolation of novel therapeutic and diagnostic parasitic vectors for solid tumor cancers, ... liver cancer, ...the novel intracellular parasite vectors; methods for the isolation of the novel vectors; genetic engineering of the isolated vectors; and methods for use of the novel vectors as well as other vectors in treatment or detection of solid malignant tumors, including metastatic tumors and tumor cells"

Instant claim 5-6 , 23-24 : Listeria see col. 89, claim 135-136, claim 141, claim 143 "genetically engineered", see claim 145 "repeating" claim 141,

described the use of *Listeria monocytogenes* as a vaccine for the immunization of mice against lethal challenges with tumor cells expressing the same antigen expressed by the Listeria vaccine. In addition, they showed regression of established tumors when immunized after tumor development in an antigen specific T-cell-dependent manner.

see col. 4, lines 30-33;

Instant claim 9, 27: administered via oral, parenteral ("The vectors of the present invention can be **administered** by a number of routes, including but not limited to: orally, topically, injection including, but limited to intravenously, intraperitoneally, subcutaneously, intramuscularly, intratumorally, i.e., direct injection into the tumor, etc").

1. Pawelek et al inherently anticipates the instantly claimed invention as now claimed. Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re

Fitzgerald et al., 205 USPQ 594

2. Inherently the reference anticipates the now claimed invention. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states AArtisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. AThe Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art≅.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINNY PORTNER whose telephone number is (571)272-0862.

The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginny Portner/
Examiner, Art Unit 1645
June 5, 2009

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645